

2017 Special 301 Out-of-Cycle Review of Notorious Markets
Federal Register Docket Number USTR-2017-0015 (82 FR 38987)

SUBMISSION

Thank you for considering the Alliance for Safe Online Pharmacies' (ASOP Global) comments in response to United States Trade Representative's (USTR) request for comments on the 2017 Special 301 Out-of-Cycle Review of Notorious Markets. ASOP Global is a 501(c)(4) social welfare organization that seeks to protect patient safety globally and ensure patient access to safe and legitimate online pharmacies in accordance with applicable laws. ASOP Global is active in the United States, Canada, Europe, India and in Asia. For more about ASOP Global see www.BuySafeRx.Pharmacy.

These comments are in response to USTR's 2017 request for comments "concerning examples of online and physical notorious markets, including foreign trade zones that allegedly facilitate substantial trademark counterfeiting and copyright piracy."¹ Although illegal online pharmacies typically are involved in intellectual property right violations, ASOP Global believes the global plague of illegal online pharmacies is fundamentally a public health issue, not one of intellectual property rights. Put a different way, any illegal online pharmacy engaged in IP violations is often engaged in behavior that simultaneously puts the public health at risk, including but not limited to the sale of counterfeit, falsified, substandard or unapproved medicines, and/or the sale of prescription drugs to consumers without a prescription. It is in this public health context that we submit these comments and urge USTR and other government partners to take actions that will help curb the global patient safety threat caused by illegal online pharmacies.

ASOP Global appreciates USTR addressing the issue of rogue registrars facilitating illegal online pharmacies in its 2014, 2015 and 2016 Notorious Market Reports. USTR's action drew global attention to the issue of "safe haven" registrars which knowingly license domain names to illegal online pharmacies. USTR's actions have increased global pressure on registrars to take action. While it is important to emphasize a majority of registrars that act responsibly and voluntarily terminate services to illegal online pharmacies, we encourage USTR to continue to send a message to registrars and marketplaces that turn a blind eye to, or welcome, illegal online pharmacies.

BACKGROUND

While the Internet has provided immeasurable societal benefits, it has also exposed global consumers to the hazards of illegal online pharmacies peddling "medicines" that may be counterfeit, adulterated, misbranded, and/or unapproved. The following statistics evidence the scope of the global problem:

- At any one time there are 35,000 – 45,000 active online pharmacies (LegitScript);
- 96% of websites offering to sell drugs are illegitimate and operating in violation of applicable U.S. laws and pharmacy practice standards (National Association of Boards of Pharmacy);

¹ <https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-17287.pdf>

- The Internet is the world’s largest marketplace for counterfeit drugs as 50% of the prescription medicines sold online by websites that hide their physical address are counterfeit (World Health Organization);
- Every month, approximately six hundred new illegal online pharmacy sites go live (LegitScript);
- 33% of surveyed consumers have previously purchased prescription medications from an online pharmacy website for themselves or someone under their care, and 55% have or would consider buying medicine online. (ASOP Global);
- Of the prescription medications being purchased online, nearly 60% are chronic illness and/or maintenance drugs for diseases such as HIV/AIDS, hypertension, hypercholesterolemia, etc. (LegitScript);
- In a two week period there were over 45,000 tweets that promoted the purchase and non-medical use of prescription drugs through an actively marketed illegal online pharmacy (Timothy Mackey, University of California San Diego); and
- Nearly 91% of first-page search results led users to an illegal online pharmacy selling controlled substances such as prescription opioids, often without a valid prescription (National Association of Boards of Pharmacy).

THE IMPORTANCE OF DOMAIN NAME REGISTRARS

In the virtual space of the Internet, there is no door for police to break down or warehouse for them to raid. Rather, law enforcement officials who wish to shut down illegal online pharmacies must engage in an often long back-and-forth process with the courts and the domain name’s registrar. In the interim, criminals operate with ostensive impunity – selling more and more illegitimate and dangerous drugs to consumers – unless and until domain name registrars (registrars), the entities that license the domain names, step in. As explained below, registrars have both the ability and authority to help stop the problem of illegal online pharmacies.

Per the contract² between registrars and the Internet Corporation for Assigned Names and Numbers (ICANN), registrars have the ability to voluntarily lock and suspend illegitimate websites. ICANN explicitly stated so in a [2012 letter](#):

“Nothing in the Registrar Accreditation Agreement (RAA) prohibits a registrar from suspending a domain name if under the applicable laws or in accordance with terms of the registration agreement the registrar deems such suspension is appropriate. In such circumstances, the registrar does not need a court order or a UDRP decision directing it to suspend a domain name.”

This authority ought to be wielded to combat the public health threat of illegal online pharmacies. If the health and safety concerns of patients don’t demand this type of action, what could?

Most registrars have recognized they must not allow criminals to use their platforms to endanger patients. Indeed, this year ASOP Global awarded Realtime Register and Rightside the first-ever “[Internet Pharmacy E-Commerce Patient Safety Award](#)” at ICANN57 in Copenhagen. Other examples of good actor registrars include GoDaddy (US) , Internet.bs (Bahamas), Blacknight (Ireland), IP Mirror

² See 2013 Registrar Accreditation Agreement, ICANN (June 27, 2013), <https://www.icann.org/en/system/files/files/approved-with-specs-27jun13-en.pdf>; 2009 Registrar Accreditation Agreement, ICANN (May 21, 2009), <https://www.icann.org/resources/pages/ra-agreement-2009-05-21-en>.

(Singapore), PDR Ltd. d/b/a PublicDomainRegistry.com (India) Networking4All (Netherlands), 1&1 Internet AG (Germany), and recently BizCN (China), which was referenced in the USTR's 2014 Notorious Markets report. These registrars have policies that prohibit domain names from being used in furtherance of criminal activity. When they receive a complaint about illegal online drug sales, they take the complaint seriously and act on the information, proactively locking and suspending the domain names of illegal online pharmacies. These registrars are to be commended for doing so and illustrate why registrars as a whole should not be considered a notorious market.

Still, too many registrars have chosen to ignore, and even support, these illegal online pharmacies. Individually, these domain name registrars constitute "safe havens" for criminal activity and should be considered a notorious market, something evidenced in the USTR's categorization of registrar Rebel in their 2015 Notorious Markets List and Nanjing Imperiosus Technology Co. in 2016. To those registrars, the promise of steady income from criminals and low risk of law enforcement action allows them to overlook the countless patients being harmed through their neglect. This willful blindness should not be tolerated, especially where such inaction threatens public health.

ONLINE MARKETPLACES – ANOTHER THREAT TO PATIENTS

Online marketplaces like Amazon, eBay, and Alibaba are increasingly important conduits of global trade. And as in the registrar industry, there are good actors and bad actors in the online marketplace space. Acknowledging they are not licensed pharmacies, most marketplaces specifically prohibit the trade in prescription (and even over-the-counter) pharmaceuticals on their platforms. A growing number have robust screening systems to limit the appearance of illicit drugs in their listings. In the event a listing is missed, having it removed is typically a straightforward process. Certain marketplaces, however, including Indiamart (www.indiamart.com), defy these norms to cash in on selling illegal pharmaceuticals to U.S. patients.³

Indiamart is one of India's largest online marketplaces.⁴ The marketplace facilitates substantial trade in illegal pharmaceuticals, including cancer and other potentially life-saving medications. In filling orders, Indiamart or its suppliers deliver to U.S. customers either:

1. **Diverted versions** of the advertised drug manufactured for foreign markets and transported without the requisite quality controls; or
2. More commonly, an altogether different Indian branded or generic drug purportedly treating the same condition, **unapproved by the FDA and again transported without the requisite quality controls.**

Additionally, these drugs often **do not contain accurate or complete information concerning the product, its purpose, side effects, dosage, or administration**, leading to dangerous results for patients.

The scale of illegal pharmaceuticals advertised on Indiamart is substantial. One pharmaceutical manufacturer identified hundreds of listings of its cancer medications on Indiamart which, as a result of the enforcement challenges described below, it is still struggling to have removed.

³ While the trade of illegal pharmaceuticals on the Indiamart marketplace is substantial and poses a significant health threat to the public, it is important to note that much of its business may otherwise be legitimate.

⁴ According to Emerge Blog (<https://emergeapp.net/traditional-businesses/best-b2b-marketplaces-in-india/>), the marketplace serves as a platform to 1.5 million suppliers generating sales to over 10 million buyers.

Indiamart shields itself from pharmaceutical companies' complaints through two defensive strategies. First, unlike reputable online marketplaces in the United States and elsewhere which ban the trade of pharmaceuticals, Indiamart disclaims all liability for violations of prescription drug laws in its terms of use. Indiamart stipulates that (a) suppliers "shall be solely responsible and shall bear all the liabilities" with regard to selling drugs without a prescription, and (b) users indemnify and hold harmless Indiamart from any liabilities incurred through "any illegal sales of drugs and/or medicines." Indiamart cites this language when rejecting complaints seeking removal of prescription drug listings on the basis that they violate applicable regulations.

Consequently, pharmaceutical companies can only obtain removal of Indiamart's dangerous prescription drug listings on trademark and copyright infringement grounds. Here Indiamart employs its second defensive strategy – it delays, stonewalls, and even ignores complaints. Complainants are forced to submit their complaints multiple times before they are addressed, and Indiamart will often reply that the issues should be taken up with the numerous suppliers individually. Indiamart's efforts to blame suppliers are particularly disingenuous since suppliers' webshops are often hosted on Indiamart's system and utilize the same Indiamart template web design. Even when it does address a complaint directly, Indiamart will issue burdensome requests for information to deter a complainant from pursuing the matter. When such information is provided, Indiamart will only go so far as to request that the supplier remove the product voluntarily – it does not forcibly remove listings nor does it terminate the accounts of repeat offenders. Even in the best case, Indiamart's handling of complaints proceeds in an exceedingly slow fashion, with months passing before listings are removed.

All the while, Indiamart distributes dangerous and illegal prescription drugs, purportedly addressing serious conditions like cancer, to vulnerable and misled U.S. patients. Indiamart's activities constitute counterfeiting, misbranding, false advertising, and fraud on a vast scale and present a significant threat to public health.

RECOMMENDATIONS

1. Rogue Internet registrars – those that knowingly facilitate illegal online pharmacies – epitomize the types of notorious markets that USTR admirably seeks to combat, and they should be clearly branded as such. To that end, below are the top five rogue registrars of 2017 in order of those hosting the most illegal online pharmacies according to LegitScript data. The organizations below, unlike the majority of the registrar community, have been non-responsive to abuse notifications. These organizations consistently refuse to cut off services to rogue internet pharmacies regardless severity of the infraction.⁵ ASOP Global recommends these five registrars be placed on USTR's 2017 Notorious Markets List.

⁵ Information regarding the "Registrar Clustering Data" was provided at ASOP Global's request for illegal online pharmacy clustering by LegitScript in a memo received on 18 September 2017.

Registrar	Country of Operation	gTLD Market Share	Known Online Rogue Internet Pharmacies
Rebel Ltd. (a division of Momentous)	Barbados	105,783	4,065
Hosting Concepts B.V. dba OpenProvider	Netherlands	304,131	2,530
Gransy s.r.o d/b/a subreg.cz	Czech Republic	168,719	855
JSC Registrar R01	Russia	27,329	815
Epik Inc.	United States	232,338	550

Source: LegitScript memo to ASOP Global regarding Online Pharmacy Registrar Clustering; September 18, 2017

Among roughly 900 companies with registrar accreditations, these five registrars are estimated to sponsor roughly 25% of all illegal online pharmacy domain names, and most have repeatedly been notified by private organizations as well as regulatory authorities or their designated representatives about domain names that continue to be used to sell illegal drugs unimpeded. Approximately 80% of all illegal online pharmacy sites are hosted within 11% (100) of registrars.

By continuing to place rogue registrars on the 2017 Notorious Markets List, as was done in 2014, 2015, and 2016, the U.S. Government will be sending a clear message—to both consumers and bad actors—that these devious activities cannot and must not be allowed to continue.

- ASOP Global also recommends Indiamart.com be placed on USTR's 2017 Notorious Markets List for the reasons outlined above.

The Alliance for Safe Online Pharmacies thanks you for considering these comments.

Regards,



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